

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,)	
JANSSEN, L.P., and)	
SYNAPTECH, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. Action No. 05-356-KAJ
)	
TEVA PHARMACEUTICALS USA, INC.)	
and TEVA PHARMACEUTICAL)	
INDUSTRIES LTD.,)	
)	
Defendants.)	

**JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P.,
AND SYNAPTECH, INC.'S REPLY TO COUNTERCLAIMS**

Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs"), by their attorneys, reply to the Counterclaims of Teva Pharmaceuticals USA, Inc. ("Teva USA"), as follows:

1. Paragraphs 1-37 of Teva USA's Answer and Counterclaims are not part of the Counterclaims and require no response by Plaintiffs.
2. In response to Counterclaim Paragraph 1, Plaintiffs admit that Teva USA has filed counterclaims seeking declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202. Plaintiffs deny that Teva USA's claims are valid or have merit.
3. In response to Counterclaim Paragraph 2, Plaintiffs admit that this Court has jurisdiction over these counterclaims pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 1331 and 1338(a).

4. In response to Counterclaim Paragraph 3, Plaintiffs admit that venue is proper in this Court pursuant to 28 U.S.C. § 1391.

5. In response to Counterclaim Paragraph 4, Plaintiffs admit that a justiciable controversy exists between the parties hereto with respect to validity and infringement of certain claims of US. Patent No. 4,663,318 (“the ‘318 patent”). Plaintiffs deny the remaining allegations set forth in Counterclaim Paragraph 4.

6. In response to Counterclaim Paragraph 5, Plaintiffs admit that Janssen, L.P. is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base. Plaintiffs deny the remaining allegations set forth in Counterclaim Paragraph 5.

7. In response to Counterclaim Paragraph 6, Plaintiffs admit that Janssen, L.P. or its predecessor caused the ‘318 patent to be listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) as a patent which claims the drug for which Janssen, L.P. or its predecessor submitted NDA No. 21-169 or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, or in the method of using the drug. Plaintiffs further admit that Synaptech, Inc. is the owner of the ‘318 patent and Janssen, is the exclusive licensee. Plaintiffs deny the remaining allegations set forth in Counterclaim Paragraph 6.

8. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Counterclaim Paragraph 7,

and on that basis deny the allegation set forth therein. Plaintiffs state that Teva USA has asserted that “Teva USA submitted its ANDA No. 77-587 to obtain FDA approval to engage in the commercial manufacture, use and sale of Eq. 4 mg base, 8 mg base, and 12 mg base galantamine hydrobromide tablets, prior to the expiration of the ‘318 patent.”

9. In response to Counterclaim Paragraph 8, Plaintiffs admit that Teva USA sent letters dated April 22, 2005 (“Notification Letters”) to Janssen Pharmaceutica N.V., Janssen Pharmaceutica Products, L.P., and/or Synaptech, Inc., notifying each that Teva USA’s ANDA No. 77-587 was received by the FDA, and that Teva USA’s ANDA contained a “paragraph IV certification” that the ‘318 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Teva USA’s ANDA.

10. In response to Counterclaim Paragraph 9, Plaintiffs admit that on June 3, 2005, Plaintiffs filed the instant suit asserting infringement of the ‘318 patent.

11. Plaintiffs reply that Counterclaim Paragraph 10 contains a legal conclusion. To the extent that Teva USA intended to assert a factual allegation, Plaintiffs respond that they are without knowledge or information sufficient to form a belief as to the truth of the allegation, and on that basis deny the allegation.

First Counterclaim

12. In response to Counterclaim Paragraph 11, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

13. Plaintiffs deny the allegations set forth in Counterclaim Paragraph 12.

Second Counterclaim

14. In response to Counterclaim Paragraph 13, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

15. Plaintiffs deny the allegations set forth in Counterclaim Paragraph 14.

16. Plaintiffs deny that Teva USA is entitled to any of the relief it has requested.

17. Any allegation not specifically admitted is denied.

Affirmative Defense

18. Teva USA's Counterclaims are barred in whole or in part because they fail to state a cause of action upon which relief may be granted.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Teva USA's Counterclaims and each and every Prayer for Relief contained therein;
- B. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims;
- D. A judgment including each and every Prayer for Relief sought by Plaintiffs in the Complaint; and

E. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ John G. Day

Steven J. Balick (No. 2114)
John G. Day (No. 2403)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
Tel: 302-654-1888
Fax: 302-654-2067
Sbalick@ashby-geddes.com
Jday@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Jeffrey B. Elikan
Laura H. McNeill
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Dated: July 13, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of July, 2005, the attached **JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'S REPLY TO COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

Josy W. Ingersoll, Esquire
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391

HAND DELIVERY

Daniel F. Attridge, P.C.
Kirkland & Ellis LLP
655 15th Street, N.W.
Washington, DC 20005-5793

VIA FEDERAL EXPRESS

/s/ John G. Day

John G. Day